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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/846,328	04/30/2001	George Jackowski	2132.051	3127

21917 7590 09/19/2005

MCHALE & SLAVIN, P.A.
2855 PGA BLVD
PALM BEACH GARDENS, FL 33410

EXAMINER

ZEMAN, MARY K

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/846,328

Applicant(s)

JACKOWSKI ET AL.

Examiner

Mary K. Zeman

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 36-43 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 36-43 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

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DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1631, Examiner **Mary K. Zeman**.

Claims 1, 36-43 are pending in this application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/27/05 has been entered.

The examiner apologizes for the incorrect notice of abandonment which was mailed in this application.

The amendments to the claims and the specification, filed 6/27/05 have been entered and considered.

The indicated allowability of claim 1 is withdrawn in view of the newly discovered reference(s) to Roehr (1988) and Laussac (1985). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Laussac et al. (1985).

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Claim 1 is drawn to a peptide consisting of residues 2-25 of SEQ ID NO: 1. The limitations "diagnostic for insulin resistance" and "biomarker" are inherent properties of the peptide, and do not impart any particular structural changes to the natural amino acid structure.

Laussac et al. (Laussac, J-P. et al. International Journal of Peptide Protein Research (1985) Vol. 26, No. 4 pages 425-428) discloses a peptide consisting of residues 1-24 of the human serum albumin peptide. This peptide is the same as residues 2-25 of SEQ ID NO: 1. The peptide is used in Mass Spectra experiments, and is therefore the same composition as being claimed in claim 1.

SEQ ID NO: 1, residues 2-25 DAHKSEVAHRFKDLGEENFKALVL

Laussac, residues 1-24 DAHKSEVAHRFKDLGEENFKALVL

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Roehr et al. (1988).

Roehr et al. (Roehr, U. et al. Liebigs Annalen der Chemie (1988) Vol. 9 pages 881-4, ABSTRACT ONLY) discloses a peptide consisting of residues 1-24 of the human serum albumin peptide. This peptide is the same as residues 2-25 of SEQ ID NO: 1. The peptide is used in Mass Spectra experiments, and is therefore the same composition as being claimed in claim 1. Only the abstract is available. A full copy of the article, and any relevant translations, will be made of record as soon as possible.

SEQ ID NO: 1, residues 2-25 DAHKSEVAHRFKDLGEENFKALVL

Roehr, residues 1-24 DAHKSEVAHRFKDLGEENFKALVL

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 36-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the metes and bounds of “diagnostic for insulin resistance” in reference to a short peptide, are unclear. This phrase appears to recite an inherent property of the peptide, and does not further limit the structure itself.

In claim 36, the metes and bounds of “in a manner effective to maximize elucidation of discernible fragments...” are unclear. This is not a positive active method step which clearly sets forth how this particular method step is to be carried out. While the claim are read in light of the specification, limitations from the specification cannot be read into the claims. This entire phrase appears unnecessary. Step c) appears to be unnecessarily wordy: The term “recognition” implies a process in the human brain, and not a computerized step. The profile does not “display” anything, “characteristic profile” is a relative term which appears to be changeable, and the end of the claim sets forth “is diagnostic for insulin resistance” which appears to have little to do with the rest of the claim. Steps which clearly “a) obtain a sample; b) perform mass spectrometry on the sample, c) identify the presence or absence of the peptide consisting of residues 2-25 of SEQ ID NO: 1, and diagnose insulin resistance based on the presence of said peptide in the sample profile...” would be more clear.

In claim 41-42, if the antibody is from a sample from a patient, how is it bound to a solid support?? It would appear applicant intends an antibody which can bind the peptide, and not an antibody present in the sample, but the claim is not so limited. Similarly in claim 43, how does one label the antibody in the patient sample?

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jarrett USP 4,687,808 provides kits comprising human serum albumin and labeled goat anti-human IgG. This labeled IgG would be expected to have antibodies to human serum albumin. SEQ ID NO: 1 consists of the first 24 residues of human serum albumin.

Carlson et al. USP 5,532,136 discloses kits comprising naturally occurring polypeptides which bind cations such as human serum albumin and antibodies to human serum albumin which would be expected to bind the claimed polypeptide. The antibodies can be labeled or immobilized to a substrate.

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Ohe et al. USP 4,837,170 discloses compositions or kits which comprise human serum albumin, and antibodies to that polypeptide which would be expected to bind the claimed peptide.

Jackowski USP 6,620,786 claims a peptide which encompasses SEQ ID NO: 1 for the same use. This patent claims 2-27 of SEQ ID NO: 1. The peptides are the SAME from 2-24. The same methods of use are claimed.

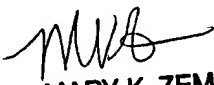
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on (571) 272 0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


MARY K. ZEMAN
PRIMARY EXAMINER
Aul631
9/21/05